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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,425	06/20/2005	Hans List	WP21690 US	8024
23690 7590 11/10/2008 ROCHE DIAGNOSTICS OPERATIONS INC. 9115 Hague Road Indianapolis, IN 46250-0457				
EXAMINER				
WHITE, DENNIS MICHAEL				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
11/10/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,425

Applicant(s)

LIST ET AL.

Examiner

DENNIS M. WHITE

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
4a) Of the above claim(s) 18-33 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-17 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 20 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 09/29/2005, 07/10/2008
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of claims 1-17 in the reply filed on 10/22/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 18-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/22/2008.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al (USP 4,163,643).

Regarding claims 1-2 and 17, Hunter et al teach a discrete sample analysis apparatus ("detecting unit") comprising a piezoelectric vibratory conveyer ("transport unit comprises at least one piezoelectric element") to convey samples in a tube ("test element") comprising a collar section 97 ("carrier") and lower section 97 to contain the sample ("evaluation area") to detectors 58 and 59 ("detector") (col. 5 lines 1-10, Fig. 3: 58 and 59). Computing equipment ("evaluation unit") is used to take the measured data

and calculate the concentration of the antigen. The transport of the tube is formed to be arrested ("stopped") when at detectors 58 and 59 (col. 2 lines 55-60).

Regarding claim 3, Hunter et al teach the tubes present in a sample store module 23 ("magazine housing") (col. 7 lines 45-64).

Regarding claim 4, Hunter et al teach the detectors are along the vibratory track (Fig. 3: track near detectors 58 and 59).

Regarding claim 5, Hunter et al teach the piezoelectric drive vibrating the stack of spiral units independently ("at least two piezoelectric elements that are electronically actuated independently of one another") (col. 5 lines 40-48, col. 12 lines 18-31).

Regarding claims 6-8, Hunter et al teach the piezoelectric element is controlled ("detector" is read on controller because it is used "to control") separately by the electrical input from the apparatus ("detection unit") (col. 9 lines 13-27). The same controller ("detector") initiates the detection of the sample in the tube ("detector detects the evaluation area of a test element").

Regarding claim 9, Hunter et al teach the collar of the tube is in contact with the track ("contact area of the transport unit and the carrier of the test element are made such that in a resting state of the transport unit static frictional forces act between the contact area and the carrier to such an extent that the test element is fixed in position relative to the transport unit") (Fig. 10: M and D).

Regarding claim 10, Hunter et al teach a gate mechanism ("contact sensor") which allows for transport ("activates the transport unit") of the tube, which is in contact with the track ("when the test element contacts the contact area of the transport unit").

Regarding claim 11-12, Hunter et al teach the transport unit is arranged on a vertical pillar 118 which allows the spiral units to undergo torsional oscillation ("rotation"). The pillar is fully capable for bearing and positioning a reel and a test strip tape wound onto a reel.

Regarding claim 13-14, and 16, Hunter et al teach a method for transporting a tube ("test element") in an analytical system comprising contacting a tube ("test element") directly with a contact area of a vibratory piezoelectric transport unit in an analytical system, and prior thereto activating a piezoelectric element of the transport unit such that the contact area of the transport unit is vibrated, transporting the test element due to the vibrated contact area along a predetermined transport path in the analytical system and stopping the transport process of the tube ("test element") such that the test element is positioned at detectors 58 and 59 ("predetermined site in the analytical system" "detection site" "detection unit for detecting at least one signal changed by an analyte") (col. 12 lines 18-31). The computing equipment ("evaluation unit") is used to take the measured data and calculate the concentration of the antigen ("determine at least one analyte in the sample based on the at least one signal")

Regarding claim 15, Hunter et al teach the tube is placed in a storage module 23 ("test element is returned into a magazine").

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishizaka et al (USP 5,077,010) in view of Kitamoto et al (USP 4,875,610).

Regarding claim 1, 13-14, 16-17, Ishizaka et al teach biochemical analysis apparatus and method ("analytical system for determining an analyte in a sample") comprising providing a measuring device for measuring the optical density produced by a color reaction of a long test film 3 ("a detection unit for detecting at least one signal

that has been changed by an analyte in a sample") and the measurement results are fed to a computer 20 ("evaluation unit to determine at least one analyte in the sample based on the at least one signal") and a motor to rotate a drive a reel of the long test film ("transport unit with a contact area wherein the contact area is suitable for directly or indirectly contacting the analytical system with a test element on which the sample can be applied" "for transporting a test element in an analytical system comprising contacting a test element directly or indirectly with a contact area of a transport unit in an analytical system"). The test film ("test element") is transported along a defined transport path in the analytical system as soon as the contact area of the transport unit is directly or indirectly contacted with a test element. The test film is mounted on a cassette like those used in audio and video cassette tapes (col. 22 lines 42-51, col. 35 lines 35-54). Ishizaka teach the method further comprising sample application, incubation, and measurement is carried out at a single position ("stopping of the transport process of the test element such that the test element is positioned at a predetermined site in the analytical system" "positioned relative to a detection site of a detection unit of the analytical system") (col. 11 line 56-col. 12 line 9).

Ishizaka et al is silent that the transport unit comprises at least one piezoelectric element which vibrates the contact area of the transport unit.

Kitamoto et al teach a method and system for driving tape in a cassette comprising a piezoelectric elements 1 and 2 to produce an ultrasonic oscillations to advance the tape ("activating a piezoelectric element of the transport unit such that the contact area of the transport unit is vibrated, transporting the test element due to the

vibrated contact area along a predetermined transport path in the analytical system"). It is advantageous to use this driving system in order to overcome the tape meandering, twisting or being stretched by tension of the conventional capstan and pinch roller.

It would have been obvious to one of ordinary skill in the art to substitute the motor of Ishizaka et al with the piezoelectric elements of Kitamoto et al in order to provide a driving means that advances the tape without meandering, twisting or being stretched by tension caused by conventional rotating motors.

Regarding claim 2, Ishizaka/Kitamoto teach a test film 210 with a support 211 and an analysis region 214 ("the test element wherein the test element comprises a carrier and an evaluation area on which the sample is applied").

Regarding claim 3, Ishizaka/Kitamoto teach the test film is in a cassette 1 ("test element is present in a magazine housing").

Regarding claim 4, Ishizaka/Kitamoto teach a detection site is located in the analytical system along the transport path (Fig. 4: 57).

Regarding claim 5, Ishizaka/Kitamoto teach two piezoelectric elements 1 and 2 can comprise a piezoelectric element pairs, each pair comprising first and second piezoelectric elements 11 and 12. These elements alternate with each other from alternating electric sources Ea and Eb ("that are electronically actuated independently of one another") in order to create a traveling wave (Kitamoto: col. 2 line 57-col. 3 line 9).

Regarding claim 6 and 10, Ishizaka/Kitamoto teach in which the driving means such as the piezoelectric element is controlled by a tape position detecting means ("detector" "contact sensor which activates the transport unit when the test element

contacts the contact area of the transport unit"); (Ishizaka: Fig. 4: 56 "photoelectric switch", col. 12 lines 9-39; Kitamoto: col. 4 line 59-col. 5 line 6).

Regarding claim 7, Ishizaka/Kitamoto teach the detector is a component of the detection unit (Fig. 4: 55-57).

Regarding claim 8, Ishizaka/Kitamoto teach the detector detects holes or markings on the evaluation area of a test film ("element") (Ishizaka: col. 12 lines 9-39).

Regarding claim 9, Ishizaka/Kitamoto teach the contact area of the piezoelectric elements ("transport unit") and the test film support ("carrier of the test element") are made such that in a resting state of the transport unit static frictional forces act between the contact area and the carrier to such an extent that the test element is fixed in position relative to the transport unit.

Regarding claim 11, Ishizaka/Kitamoto teach a reel 6 is mounted on a rotatable shaft ("a carrier element to rotate" "which is suitable for bearing and positioning a reel"). The shaft is fully capable of being rotated by the piezoelectric elements because the tape would be advanced causing the reel to rotate and thus the shaft to rotate.

Regarding claim 12, Ishizaka/Kitamoto teach the use of long test film on a reel ("which is suitable for using a test strip tape wound onto the reel").

Regarding claim 15, Ishizaka/Kitamoto teach the step wherein the test film ("element") is returned into a used film cassette part 2 ("test element is returned into a magazine").

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

/dmw/